

## **REMARKS**

Claims 1-13, 17, and 24 were canceled earlier due to restrictions imposed by the Examiner and required to be withdrawn from consideration. Claim 14 has been amended to specify that the primary drug is different from the secondary drug, the tie layer has a polymer such that an adhesive does not enter the breathable material due to crushing part of the breathable material during embossing and that the multilaminate backing construction is at the top of a transdermal drug delivery device such that the base layer of the multilaminate backing construction does not contact the skin when the device is in use. Claim 31 has also been amended to specify that the primary drug is different from the secondary drug, the tie layer has a polymer such that an adhesive does not enter the pores in the breathable material in the crushing of some of the pores during embossing and that the multilaminate backing construction is at the top of a transdermal drug delivery device such that the base layer of the multilaminate backing construction does not contact the skin when the device is in use. Support for the amendment of claim 14 and 31 can be found, for example, in the specification on paragraphs 6 and 32 and the drawings. New claim 37 is added to a method of making a transdermal device having multilaminate backing, primary drug reservoir and protective layer. Support for the new claim can be found, for example, in the specification in paragraph 48 and in the drawings. New claim 38 is added to a method of making a transdermal device having multilaminate backing, primary drug reservoir and protective layer and including in the secondary drug reservoir an antagonist of the primary drug. Support for the new claim can be found, for example, in the specification in paragraphs 33 and 48 and in the drawings. New claim 39 is added to a method of making a transdermal device having multilaminate backing, primary drug reservoir and protective layer and including an opioid as the primary drug. Support for the new claim can be found, for example, in the specification in paragraphs 48 and 49 and in the drawings. No new matter is added in the amendment or the new claims. Thus, claims 14-16, 18-23, 25-32 and 37-39 are pending.

## **Suggested Restriction**

The new claims address methods of making transdermal devices. It is suggested that they be restricted out that claim 37 be in a group drawn to a method of making a transdermal device

with multilaminate backing, claim 38 be in a group drawn to a method of making a transdermal device with a drug and an antagonist thereto; and claim 39 be in a group drawn to a method of making a transdermal device with an opioid.

### **Telephone Interview**

Applicant notes with appreciation the courtesy extended by the Examiner to Applicant's attorney, Philip Yip, in the telephone interview of October 24, 2007. During the telephone interview, the claim objection on obviousness type double patenting and the Kydonieus reference and the Steinborn were discussed. Philip Yip argued that neither the Steinborn device nor the Kydonieus device is a backing placed in a transdermal device wherein the adhesive is not attached to the skin. Discussion was also made about adding new claims and possible restrictions. No agreement on claim allowance was arrived at.

### **Double Patenting**

The Examiner rejected claims 14-16, 18-23, 25-30 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-9, 13, 21, 43, 54-57, 66, 90-92, 97-99 of copending Application No. 10/420,428 in view of Steinborn et al. US6080421. Applicant respectfully traverses the rejection.

It is submitted that although copending Application No. 10/420,428 and the Steinborn et al. patent are about transdermal drug delivery system, neither of them have a multilaminate tie layer between a top layer and a barrier base layer. According to the Webster's Ninth Collegiate Dictionary (Merriam Webster 1989), "laminating" means "to make by uniting superposed layers of one or more materials" or as "to unit (layers of material) by adhesive or other means". The noun "lamine" is defined as "a product made by laminating". Thus, a "multilaminate" must include at least two distinct layers together. Absent the teaching of the present invention, a person skilled in the art will not think of combining the cited references to arrive at the present invention, which has a tie layer that is multilaminate.

Further, both cited references are about transdermal drug delivery systems, not backings. Neither of them talks about having a backing having a tie layer such that during embossing adhesive does not enter the breathable backing.

It is noted that copending Application No. 10/420,428 is about, as Steinborn, a transdermal drug delivery device, not a backing. In Application No. 10/420,428, the antagonist reservoir (which is made of adhesive matrix) is right next to the porous backing (see the figures of 10/420,428) and thus if the systems were embossed, material from the antagonist reservoir will enter the pores. This is different from the present backings of the present invention, which has a tie layer such that adhesive does not enter the breathable backing during embossment.

Further, in copending Application No. 10/420,428, there is no mention of embossing, so the specification does not support claims about embossment, whereas in the pending claims of the present application, the backing is embossed.

Further, in both copending Application No. 10/420,428 in view of Steinborn et al. US6080421, the adhesive in these systems is to be applied to the skin when the device is in use, which is different from the present invention.

Thus, even if copending Application No. 10/420,428 were to be combined with Steinborn et al. as asserted by the Examiner and the system were embossed, the adhesive is to be applied to the skin when the device is in use, which is different from the present invention and the antagonist reservoir material will enter the porous backing during embossing, which is different from the present invention.

Withdrawal of the objection is requested.

Nevertheless, Applicant reserves the right to submit a terminal disclaimer later if Applicant thinks it may speed the issuance of a patent.

### **35USC §103(a) rejection**

Claims 14, 15, 18-23, 25, 26, 28, and 30 25 were rejected under as being unpatentable over Kydonieus et al. (US4758434) in view of Steinborn et al. (US6080421) and evidenced by Gale et al. (US4904475). Insofar as the rejection is maintained on the amended claims, Applicant respectfully traverses the rejection.

Regarding claims 14, 19, and 30, the Examiner asserted that the recited structural relationship between the layers are not given any patentable weight as outer layer/tie layer/base layer. Applicant submits that anyone skilled in the art clearly understands that the multilaminate backing construction of the present invention is composed of different layers of materials and is entirely different from the single layer backing of the prior art. The outer layer is a breathable material, the tile layer has a drug and ties the base layer to the outer layer and such that adhesive does not enter the breathable outer layer when embossed. Moreover, the tie layer is itself a **multilaminate** layer. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d, 180 USPQ 580 (CCPA 1974). Every element has to be considered. If the Examiner's logic were followed that different layers of different material are not given patentable weight, a rock will anticipate a house that has a roof on walls supported by a foundation.

Further, the Examiner asserted that the primary drug and the secondary drug can be considered the same because the same drug can be considered a drug or an antagonist. Applicant respectfully disagrees. In the claims we specify the antagonist is the antagonist of the primary drug. Patents are written for those skilled in the art. Those skilled in the art will not consider an agonist drug to be an antagonist of itself. If the Examiner's view is to be taken literally, then to save a patient overdosed with a narcotic a physician would give more of the same narcotic (as an antagonist) to the patient. This practice would be a sure way to invite a malpractice suit. No person skilled in the art will follow this interpretation. However, to speed the prosecution of the application, Applicant has amended the claim to specify that the primary drug and the secondary drug are different.

It is submitted that both Steinborn devices and the Kydonieus devices are transdermal drug delivery systems, not backings. The backing on the Kydonieus devices is a single layer (e.g., numeral 6 in Fig. 1), which Kydonieus said is “such as one made of plastic, moisture-proof fabric, aluminum foil, etc.” The backing is shown as a single layer in the drawing and there is no indication of the backing having a multilayered construction, much less a multilayered construction with a multilamiantie tie layer having a drug reservoir. Further, the Kydonieus backing is not embossed. Similarly, the Steinborn device is also a transdermal drug delivery system, not a backing. Although Steinborn shows a backing having two layers, the backing does not have a multilaminate tie layer. As pointed out above, a multilaminate tie layer must have two separate distinct layers. There is no such multilamiantie tie layer in either references. The word “multilaminate” means something entirely different from a single layer to one skilled in the art. Thus a multilaminate has distinct layers. If the Examiner is to assert that a single layer can be considered multilaminate by one skilled in the art, the Examiner is respectfully requested to provide literature support for that assertion.

Thus, even if one assumes that a person skilled in the art were to assumed to try to combine Kydonieus and Steinborn, such a combination will not result in a multilaminate tie layer, much less a multilaminate backing that has a multilaminate tie layer that has a secondary drug. Further, a combination of Kydonieus and Steinborn will only result in a drug delivery system to be used directly on skin, not result in a backing that is to be placed in a more complex drug delivery system wherein the base layer of the backing does not contact skin when in use. It is clear that the adhesive layer, which is the layer next to the protective liner in either the Kydonieus device or the Steinborn device are to be attached to the skin. This is entirely different from the present invention.

The Examiner asserted that it would have been obvious to emboss the outer backing layer of Kydonieus device because embossing is taught by Steinborn. However, Steinborn only talked about deforming by heat to change the shape in embossing, it is entirely silent about crushing of breathable material. Further there is absolutely no indication that there is a tie layer that does not result in adhesive entering the breathable material in embossment. A limitation cannot be rendered obvious by the complete absence of that limitation in the prior art reference.

Regarding claim 15, the Examiner asserted that in the absence of compositions for the component layers in the tie layer, the component layers are indistinguishable and therefore the single tie layer of Kydonieus's reads on the instantly claimed component layers. However, as pointed above, one skilled in the art will know that a multilaminate must have more than one layer. Additionally, Applicant has added new claim 32 specifying that the tie layer has at least two layers of different materials.

Regarding claims 18, 23, 25, and 28, the Examiner took Official notice that polypropylene microporous membrane is a common backing material for a transdermal delivery system as admitted prior art. However, Applicant traverses because microporous membrane is not used in the prior art as a layer of a multilaminate backing which has been embossed. Kydonieus might have mentioned semipermeable membrane, but he did not mention embossing. Steinborn might have mentioned embossing, but he did not mention microporous membrane. Just because two features are mentioned separately in two references does not mean they can be combined. If one feature defeats the usefulness of the other feature they should not be combined. For example, one can make a roof for a house by soldering copper sheets with an acetylene torch, and one can make a roof of wood. It would be madness to try to use a torch to solder wooden planks together to form a roof. Wood and flame are incompatible, just as embossing and breathable backing next to a pressure sensitive adhesive are incompatible. Embossing a laminate with microporous membrane next to an adhesive causes problems, as clearly described in the present invention. Thus, if one were to replace the Steinborn backing (feature item reference 1 in Fig. 1 in Steinborn) with a microporous membrane and try to emboss by pressure, one would have exactly the problem described in paragraph 6 of the present application. Applicant submits Steinborn and Kydonieus cannot be combined in the way suggested by the Examiner.

The Examiner rejected claims 20 and 26, asserting that Kydonieus' agents encompasses the our claimed agents, implying that the antagonist reads on Kydonieus's drug in the drug reservoir. However, Kydonieus's drug reservoir is a reservoir for delivery of a drug to the skin. On the contrary, the antagonist in the present invention is in the backing and is not to be delivered to the patient. The antagonist is only released when our drug device is subject to abuse. There is nothing to prevent the Kydonieus reservoir from delivering the "drug-antagonist" in the drug reservoir to the skin as delivery from the reservoir is intended by Kydonieus. Moreover, the antagonist as used in the present invention is an antagonist to a drug in the primary drug reservoir. Thus the two drugs have countering action and are not to come into contact unless the device is being abused. This mode of delivery suggested by the Examiner would deliver an antagonist with the agonist, against all conventional practices by those skilled in the art. Thus, the Kydonieus drug reservoir should not render obvious what we have in the secondary drug reservoir.

The Examiner rejected claims 21 and 22 based on Kydonieus disclosing PVC particles in the plastisol. However, as Applicant pointed out about, Kydonieus is not about a backing and the plastisol is to be attached to a patient when the device is in use, which is entirely different from the present invention.

The Examiner rejected claims 16, 31, and 32 as being unpatentable over Kydonius et al. in view of Steinborn et al. and FR2249148 because FR'148 discloses an adhesive tape of Pet film having non-tacky hot melt EVA coating on both sides. However, the FR'148 device is related to adhesive tape with pressure sensitive and is totally unrelated to transdermal delivery, much less has anything to do with the backing in which the base layer is not in contact with the skin when the backing is in use. Even if one would combine FR2249148 with Kydonius et al in view of Steinborn et al., the drug-containing adhesive would still be applied to the skin when the device is in use. Further, including hot melt adhesive as well as pressure sensitive adhesive in a tape increases the thickness of a tape, which is contrary to the conventional wisdom on desirable aesthetic characteristics.

The Examiner rejected claims 27 and 29 by asserting that Kydonieus discloses that the backing layer 34 can be made of aluminum foil which is inherently impermeable to drugs and the Examiner against asserted that the language of the claims are not given patentable weight as failing to contribute to limiting the structure and antagonist can be considered the same antagonist. Applicant respectfully point out that the backing of the present invention has a breathable outer layer and a base layer that is not permeable. The Examiner is asked to explain and provide literature support how an aluminum foil of Kydonieus can be porous and anticipate both our outer breathable layer and the impermeable base layer. In claim 27, we specifically state “antagonist to the drug.” According to J. Stenesh, Dictionary of Biochemistry and Molecular Biology, 2<sup>nd</sup> Ed., 1989, John Wiley & Sons, “antagonist” is defined as “[a] molecule, such as a drug, an enzyme inhibitor, or a hormone, that diminishes or prevents the action of another molecule or receptor site.” Thus, no person skilled in the art will consider a drug to be its own antagonist since it cannot diminish or prevent its own action. The Examiner is requested to provide literature support that a drug can be its antagonist and that including a drug and its antagonist means including only the drug to one skilled in the art.

Because of the foregoing reasons, the cited references do not render the present invention obvious. Withdrawal of the rejections is respectfully requested.

## **CONCLUSION**

Applicant submits the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC §102, §103 and §112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

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